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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,221	06/30/2006	Bruno Robert	1843.0200001/EKS/AJK	2116

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EXAMINER
DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,221	ROBERT ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/25/05*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-45, drawn to a compound comprising one or more CD1d/β2m and optionally antigen complexes and an antibody or fragment thereof specific for a cell surface marker, wherein the CD1d molecule(s) are linked to said antibody or fragment thereof.

II. Claims 46-48, drawn to a method of inducing an anti-tumor response in a mammal, or to a method of preventing or treating autoimmunity, an inflammatory disease or an infectious disease in a mammal, said method comprising administering the compound of Group I.

2. Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of a CD1d complex linked to an antibody or fragment thereof, this technical feature is not a special technical feature as it does not make a contribution over the prior art as evidenced by US 2002/0071842 A1 (IDS reference) in view of WO 01/78768 A2 (IDS reference).

US 2002/0071842 A1 discloses CD1d-IgG multimers further comprising lipid or glycolipid antigen for use in targeting T cells. US 2002/0071842 A1 discloses that an antigen for CD1d is α-GalCer, and that CD1d/antigen complexes are recognized by T cells. US 2002/0071842 A1 discloses multimerizing CD1d/antigen-IgG using avidin/biotin. US 2002/0071842 AI discloses using the multimers in vaccine formulations to treat autoimmunity, cancer or infectious diseases.

US 2002/0071842 A1 does not disclose wherein the antibody or fragment thereof is specific for a cell surface marker, nor wherein the antibody is a F(ab) or an F(ab')2 or a full-length antibody.

WO 01/78768 A2 teaches a targeted vaccine delivery system comprising one or more MHC/peptide antigen complexes (recognized by T cells) linked to an antibody which is specific for a cell surface marker such as a T cell surface marker, and use in treating cancer, infectious disease, autoimmune disease and/or allergies. WO 01/78768 A2 further teaches F(ab), full length antibodies or F(ab92 (especially Abstract and page 24).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used an antibody to a T cell surface marker as taught by WO 01/78768 A2 for MHC/peptide/antibody multimeric complexes in the complexes disclosed by US 2002/0071842 A1 for CD1d/lipid antigen/IgG multimeric complexes.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to more effectively target CD1d/peptide complexes to T cells since US 2002/0071842 A1 teaches targeting T cells and WO 01/78768 A2. teaches using antbodies or fragments thereof to target another complex recognized by T cells, *i.e.,* MHC/peptide complexes, to T cells or other cells such as tumor targets.

3. The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

4. This application contains claims directed to the patentably distinct species of CD1d-antibody complex of Group I or to the patentably distinct species of CD1d-antibody complex to be used in the method of Group II:

a. the CD1d complex is either empty OR comprises an antigen (such as recited in, for example, claims 3-6), AND

b. the antibody is either full length (as recited in claim 9) OR is a specific fragment thereof (such as recited in claims 7 or 8, AND

c. the specificity of the antibody is to a single cell surface marker such as one recited in claims 10-35 (such as for example, PSCA recited in instant claim 12), AND

d. the attachment of CD1d to the antibody or fragment thereof is one of the specific attachments recited in claims 36-43, AND

e. The compound either does OR does not further comprise a costimulatory molecule such as B7 recited in claim 45.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. For example, the antigen present in the CD1d binding site determines the interaction of NK cells specific for that antigen, whereas the specificity of the antibody determines what target cell will be bound. The antigens have different structures and the antibody combining site, particularly CDRs, have different sequences. In addition, these species are not obvious variants of each other based on the current record.

If Group II is elected, Applicant is also required to elect a single disclosed species of method for either: (1) inducing an anti-tumor response, or (2) preventing or treating autoimmunity, or (3) inflammatory disease, or (4) infectious disease in a mammal. These species are distinct because the immune response is directed to different antigens and the method treats or prevents different diseases or conditions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (*e.g.,* searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Eileen B. O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Group 1640
Technology Center 1600
January 5, 2009

/G.R. Ewoldt/
Primary Examiner, Art Unit 1644